



Manual on how a person can
**APPLY FOR A LICENSE TO
OPERATE A MEDICAL CLINIC**

BASIC INFORMATION

Version 01
October 2019

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From time to time the process to apply for a license may change, so there will be regular updates of this manual. The aim is to provide increased access to online information.

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1. Introduction

The inspectorate within the Healthcare Standards Directorate monitors, inspects and regulates medical clinics to make sure that these laboratories meet fundamental standards of quality and safety. The names of licensed laboratories are published on the website so that the public is aware as to which establishments are licensed and thus have reinforced procedures for patient safety. This list can be accessed through <https://deputyprimeminister.gov.mt/en/hcs/Pages/health-care-standards.asp>.

The Directorate puts the health of the public at the centre of its work and strives to be rigorous, fair and consistent in its approach. The aim of this document is to provide basic information to any person applying for a license to operate a medical clinic.

2. General information

- a. In Malta, medical clinics are regulated through the [Licensing of Private Medical Clinics Regulations \(S.L. 458.23\)](#) and the [Health Care Professions Act \(Chapter 464\)](#);
- b. Although S.L. 458.23 states that the ' private medical clinic ' includes a private hospital and a day care medical clinic, this does not include the medical doctor's advisory room. These guidelines also apply to the public sector, even if not specifically mentioned in S.L. 458.23.
- c. Medical services and surgical procedures are to be performed **ONLY** by registered medical practitioners, and where permitted by law by registered nurses, midwives and allied health care professionals under the prescription of a registered medical practitioner;
- d. To practice as a medical practitioner in Malta one must be qualified and registered with the Medical Council of Malta;
- e. As stipulated by the [Medical and Kindred Professions Ordinance](#), the Medical Clinic (as specified in S.L.458.23), within which a medical practitioner can practice, needs to have a valid license issued through the Superintendence of Public Health;
- f. The licensing office for medical clinics is within the Health Care Standards Directorate at the Health Regulation Department;
- g. Opening Hours are from 7am till 2.45 pm Monday to Friday;

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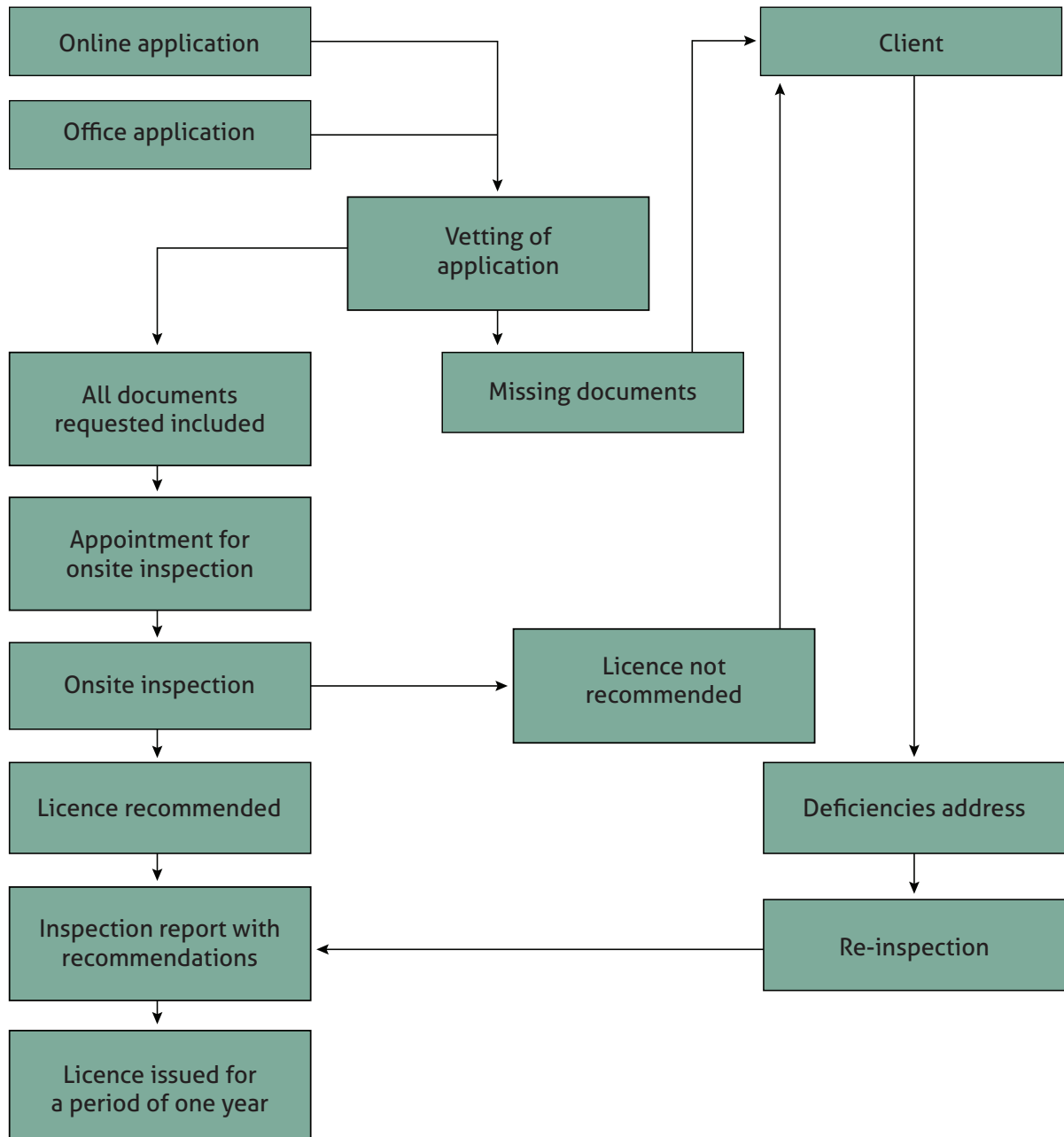
3. Applying for a license

- a. A person interested in providing services through a medical clinic must apply for a license as stipulated in [Licensing of Private Medical Clinics Regulations \(S.L. 458.23\)](#) and the Health Care Professions Act (CAP 464)
- b. New applicants must be at least eighteen (18) years of age;
- c. One can apply for a license either by completing the [application form](#) or through the online application available at: <https://hcstandardsregistration.gov.mt/>
- d. When applying for a medical clinic license, the following documents must be submitted:
 - A duly filled-in [application form](#);
 - A copy of the Medical Council of Malta registration certificate of all medical practitioners who will be working within the clinic;
 - A permit showing the proposed premises including the site plan or a declaration by an architect certifying that the premises carry a PA permit for use as a medical clinic;
 - A photocopy of the applicant's identity card;
 - An Anti Hbs titre result of any dentists, acupuncturists, physiotherapists (who perform dry needling) and podiatrists who will be working within the clinic (if applicable);
 - If applying on behalf of a company, a copy of the Memorandum of Articles together with a declaration by the Director/s of the same company indicating that license is to be issued on the applicant's name;
 - For a third-country national to practice in a medical clinic in Malta, one must apply for a work permit through Jobs Plus which can be contacted on telephone number 22201290 or e-mail: jobsplus@gov.mt;

- e.** Upon receiving the filled in application together with all the relevant documents, the licensing officer will vet the application accordingly;
- f.** At this stage an onsite inspection is organised and the applicant is informed;
- g.** An inspection team holding an authorisation badge will visit the premises. In case of a new establishment, a pre licensing visit may be requested by the applicant (recommended);
- h.** A self-assessment check-list indicating the requirements to operate a medical clinic will be sent to the applicant ten (10) days prior to the inspection. This self-assessment will guide the applicant on what the inspection team will be expecting to find during the planned visit;
- i.** During the inspection, the inspection team will verify if all conditions for licensing are satisfactory and will decide whether to recommend licensing or not;
- j.** In cases where deficiencies are identified, a meeting with the applicant to advise and highlight the deficiencies needing attention will be held, this may necessitate a follow up visit;
- k.** Once all conditions for licensing are satisfactory a license will be issued;
- l.** The license includes a set of conditions. The licensee must understand and comply with these conditions;
- m.** Once the application is approved and licensing is recommended, the client is advised to pay an annual license fee of €512.50 for Hospitals, €512.50 for a Private Clinic with overnight stay and €257.30 for a Private Day Clinic. The applicant may opt to collect the license from the Healthcare Standards Directorate (HCSD) licensing office or receive it by registered post.

4. The licensing process

The following flow chart outlines the procedure followed by the client and the inspectorate during the licensing process.



5. The medical clinic

- a. A medical clinic must have the license displayed in an area, where it can be easily observed by the public upon entering the waiting area.
- b. The premises must be kept clean, in good condition and state of repair;
- c. The medical clinic must have all the necessary equipment;
- d. The medical clinic must have adequate lighting and ventilation (Natural or mechanical);
- e. The area where procedures are carried out must provide total client privacy;
- f. The premises must have an efficient drainage system connected to a main system;
- g. Fire-fighting equipment must consist of fire extinguishers with a valid expiry date and fire blankets;
- h. A medical clinic must have a separate waiting room and when the clinic is being planned, the procedure area should only have access through the waiting room;
- i. The clinic walls must be painted with water repellent paint for easy cleaning;
- j. Toilet facilities must be available.

6. The work station

- a. Work surfaces must be kept clean and well maintained and must be regularly washed with warm soapy water and wiped with a 70% alcohol solution. Work tops should be made of an impervious material for easy cleaning;
- b. Paper towels must always be available;
- c. There should be sufficient bench space to accommodate all the equipment used during clinic procedures;
- d. A wash hand basin must be available within easy reach of the area where procedures are carried out and must be kept clean, well maintained and connected to the main drainage system. Single lever taps must have a supply of hot and cold water;
- e. Soap/suitable detergent and adequate drying facilities must be available near each wash hand basin;
- f. Client couches must be upholstered with an impervious type of material, which can be easily cleaned. Multiple couches must have a partition between them for adequate client privacy;
- g. A proper sharps container must be available within each area where procedures are carried out;
- h. A foot operated pedal bin lined with a disposable garbage bag must be available in each working station.

7. Lavatory facilities

- a. Lavatory facilities must be connected to the main drainage system and must always be kept clean and well maintained;
- b. There must be a proper functioning flushing apparatus;
- c. The wash hand basin within the lavatory room must have a supply of hot and cold water;
- d. Adequate hand washing/drying facilities must always be available;
- e. Proper ventilation must be present within the lavatory facilities (natural or mechanical);
- f. The lavatory facilities must have adequate lighting;
- g. Where possible lavatory facilities are to be accessible from the waiting room.

8. Equipment used during medical procedures

- a. Equipment used during medical procedures must be operated, maintained and serviced as per manufacturer's instructions. All documentation relating to maintenance and servicing should be made available and stored properly;
- b. Medical equipment and consumables must have a CE mark;
- c. All sharps must be disposed of in special sharps containers that are rigid, puncture-resistant, and leak-proof and must be kept upright. Clinical waste must be collected by an approved Class D waste collector.

9. Additional guidelines

- a. An updated equipment register complete with a scheduled maintenance program must be kept by the licensee;
- b. Refrigerators and other equipment should be monitored through a calibrated temperature monitoring device;
- c. An adequate first aid box is to be readily available;
- d. At least one back-up of all medical data generated, must be stored 'off-site';
- e. No medical clinic shall accept patients until the facility has the written approval and/or license issued by the Minister responsible for public health;
- f. Except as set forth below, the license is not transferable, and it shall be immediately void if the medical clinic ceases to operate, if the clinic ownership changes or if the medical clinic is relocated to a different site;
- g. In the case of a transfer of ownership, the new owners of a medical clinic shall present an application for licensure with the HCSD within the Superintendence of Public Health. In addition, the following information shall be submitted with the application:
 - A detailed description of the proposed transfer of ownership.
 - Copies of all legal documents pertinent to the transfer of ownership transaction which are signed by both the current licensed owners and the proposed licensed owners.
- h. To qualify for licensure as a medical clinic, the following are required:
 - All health care professional staff shall have documented competencies and shall be registered with the respective Council as established by the Health Care Professions Act (CAP. 464);

- A medical practitioner should be present within the premises during the post-operative time;
- There shall always be at least one registered nurse on duty in each ward or special unit patients are receiving a service as per S.L. 458.23 Licensing of Private Medical Clinics (Article 92.a)
- i. A medical clinic which intends to close voluntarily and to cease delivery of services shall notify the Superintendence of Public Health in writing. A plan for closure shall be developed which provides for the orderly transfer of patients and clinical records to another medical clinic. Such plan shall also be submitted to the Superintendent of Public Health a minimum of six months prior to closure or cessation of service delivery.
- j. The medical clinic shall notify each patient and their physicians, and any guarantors of payment at least six months prior to the voluntary surrender of a license;
- k. If the medical clinic or a component thereof ceases to operate, the licensee should inform the Directorate. In these circumstances all documents pertaining to patients or clients (medical records, results, etc.) should be given to them or their relatives in compliance with data protection regulations;
- l. The license, unless suspended or revoked, shall be renewed annually at the end of the current year. The medical clinic will receive a request for the renewal fee 30 days prior to the expiration of the license. A renewal license shall not be issued unless the licensure fee is received by the Directorate;
- m. The license may not be renewed, if current licensing standards, local rules, regulations, and/or requirements are not met;
- n. Failure to renew a license shall constitute the operation of a health care facility without a license and may result in the issuing by the HCSD within the Superintendence of Public Health of a cease and desist order, in accordance with the Medical and Kindred Professions Ordinance (Chapter 31).

